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PATENT

Attorney Docket No.: 019934-001710US

Client Reference No.: T001710US

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By: Tara N. D. 16

Tara N. Damhof

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Thomas J. Schall et al.

Application No.: 09/919,224

Filed: July 30, 2001

For: IMMUNOLOGIC ACTIVITIES OF  
RHESUS CYTOMEGALOVIRUS  
ENCODED IL-10 (AMENDED)

Customer No. : 20350

Confirmation No. 5559

Examiner: Michail A. Belyavskyi

Art Unit: 1644

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT UNDER 37  
CFR §1.97 and §1.98

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Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the references are enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

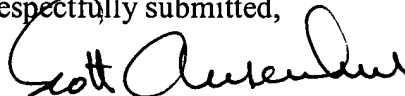
As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement.

However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Scott Ausenhus", written over the text "Respectfully submitted,".

Scott L. Ausenhus  
Reg. No. 42,271

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60236538 v1

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>			<b>Complete if Known</b>		
			Application Number	09/919,224	
			Filing Date	July 30, 2001	
			First Named Inventor	Schall, Thomas J.	
			Art Unit	1644	
Examiner Name	Michail A. Belyavskyi				
Sheet	1	of	3	Attorney Docket Number	019934-001710US

U.S. PATENT DOCUMENTS+					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code <sup>2</sup> (if known)			
	A1	US-5,770,190	06-23-1998	Bruserud et al.	
	A2	US-5,833,976	11-10-1998	Malefyt et al.	
	A3	US-5,866,134	02-02-1999	Fine et al.	
	A4	US-5,871,725	02-16-1999	Schwarz	
	A5	US-6,022,536	02-08-2000	Tadmori	
	A6				

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	B1							<input type="checkbox"/>
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	B3							<input type="checkbox"/>

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Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
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Examiner Name	Michail A. Belyavskyi				
Attorney Docket Number	019934-001710US				
Sheet	2	of	3		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	ASADULLAH, KHUSRU et al. "Interleukin-10 Therapy- Review of a New Approach" Pharmacological Reviews, 2003, pp. 241-269, Vol. 55, No. 2.	
	C2	ASADULLAH, KHUSRU et al. "Interleukin 10 Treatment of Psoriasis" Arch. Dermatol, Feb. 1999, pp. 187-192, Vol. 135.	
	C3	ASADULLAH, KHUSRU et al. "IL-10 Is a Key Cytokine in Psoriasis" J. Clin. Invest., Feb. 1998, pp. 783-794, Vol. 101, No. 4.	
	C4	DEJACO, C. et al. "In Vivo Effects of Recombinant Human Interleukin-10 on Lymphocyte Phenotypes and Leukocyte Activation Markers in Inflammatory Bowel Disease" J. Investigative Medicine, Nov. 2000, pp. 449-456, Vol. 48, No. 6.	
	C5	DHARANCY, SEBASTIEN et al. "Hepatic Deficiency of Interleukin 10 in Chronic Hepatitis C" Gastroenterology, 1000, pp. 1411-1420, Vol. 119.	
	C6	FEDORAK, RICHARD N. et al. "Recombinant Human Interleukin 10 in the Treatment of Patients With Mild to Moderately Active Crohn's Disease" Gastroenterology, 2000, pp. 1473-1482, Vol. 119.	
	C7	FRIEDRICH, MARKUS et al. "Immunomodulation by Interleukin-10 Therapy Decreases the Incidence of Relapse and Prolongs the Relapse-free Interval in Psoriasis" J. Investigative Dermatology, April 2002, pp. 672-677, Vol. 118, No. 4.	
	C8	GASHE, CHRISTOPH et al. "IL-10 Secretion and Sensitivity in Normal Human Intestine and Inflammatory Bowel Disease" J. Clin. Immunol., 2000, pp. 362-370, Vol. 20, No. 5.	
	C9	GASHE, CHRISTOPH et al. "Novel Variants of the IL-10 Receptor 1 Affect Inhibition of Monocyte TNF- $\alpha$ Production" J. Immunology, 2003, pp. 5578-5582, Vol. 170, No. 11.	
	C10	KEYSTONE, EDWARD et al. "IL-10 as a Therapeutic Strategy in the Treatment of Rheumatoid Arthritis" Emerging Therapies for Rheumatoid Arthritis, Rheumatic Disease Clinics of North America, August 1998, pp. 629-639, Vol. 24, No. 3.	
	C11	LINDSAY, J.O. & HODGSON, J.F. "Review Article: the immunoregulatory cytokine interleukin-10- a therapy for Crohn's disease?" Aliment Pharmacol. Ther., 2001, pp. 1709-1716, Vol. 15.	
	C12	LLORENTE, LUIS et al. "Clinical and Biologic Effects of Anti-Interleukin-10 Monoclonal Antibody Administration in Systemic Lupus Erythematosus" Arthritis & Rheumatism, August 2000, pp. 1790-1800, Vol. 43, No. 8.	
	C13	MOCELLIN, SIMONE et al. "The dual role of IL-10" Trends in Immunology, Jan. 2003, pp. 36-43, Vol. 24, No. 1.	
	C14	MOORE, KEVIN et al. "Interleukin-10 and the Interleukin-10 Receptor" Annu. Rev. Immunol., 2001, pp. 683-765, Vol. 19.	
	C15	NELSON, DAVID R. et al. "Interleukin 10 Treatment Reduces Fibrosis in Patients With Chronic Hepatitis C: A Pilot Trial of Interferon Nonresponders" Gastroenterology 2000;118 655-660, Published online 10 March 2000.	
	C16	OPAL, STEVEN M. et al. "Interleukin-10: Potential Benefits and Possible Risks in Clinical Infectious Diseases" Clinical Infectious Diseases, 1998, pp. 1497-1507, Vol. 27.	

Examiner Signature		Date Considered	
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.



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Sheet	3	of	3	Attorney Docket Number	019934-001710US

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	C17	OPAL, STEVEN M. & CROSS, ALAN S. "The Microbial Consequences of Antimediator Therapy for Sepsis" Sepsis, 1997, pp. 59-64, Vol. 1.	
	C18	SANDER, O. & RAU, R. "Clinical trials on biologics in rheumatoid arthritis" International J. of Clinical Pharmacology and Therapeutics, 1998, pp. 621-624, Vol. 36, No. 11.	
	C19	SCHREIBER, STEFAN et al. "Immunoregulatory Role of Interleukin 10 in Patients With Inflammatory Bowel Disease" Gastroenterology, 1995, pp. 1434-1444, Vol. 108.	
	C20	SCHREIBER, STEFAN et al. "Safety and Efficacy of Recombinant Human Interleukin 10 in Chronic Active Crohn's Disease" Gastroenterology, 2000, pp. 1461-1472, Vol. 119.	
	C21	Stedman's Medical Dictionary, 26th Edition, 1990, Definition of "Symptom", p. 1718.	
	C22	STEINHART, HILLARY "Clinical perspectives- Biologics in IBD: What's all the fuss?" Can. J. Gastroenterology, Dec. 2001, pp. 799-804, Vol. 15, No. 12.	
	C23	TILG, H. et al. "Treatment of Crohn's disease with recombinant human interleukin 10 induces the proinflammatory cytokine interferon $\gamma$ " Gut, 2002, pp. 191-195, Vol. 50.	
	C24	VAN DER POLL, TOM et al. "Endogenous IL-10 Protects Mice from Death During Septic Peritonitis" J. Immunology, 1995, pp. 5397-5401, Vol. 155.	
	C25	VAN DEVENTER, SANDER J.H. et al. "Multiple Doses of Intravenous Interleukin 10 in Steroid-Refractory Crohn's Disease" Gastroenterology, 1997, pp. 383-389, Vol. 113.	
	C26	WISSING, K. MARTIN et al. "A pilot trial of recombinant human interleukin-10 in kidney transplant recipients receiving OKT3 induction therapy" Transplantation, Oct. 1997, pp. 999-1006, Vol. 64.	

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